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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,813	12/04/2006	Thomas Stiefel	251508	9037

23460 7590 09/03/2010

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EXAMINER	
GWARTNEY, ELIZABETH A	

ART UNIT	PAPER NUMBER
1781	

NOTIFICATION DATE	DELIVERY MODE
09/03/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Chgpatent@leydig.com

ATTACHMENT TO ADVISORY ACTION

Applicants' amendment to the claims filed on 08/27/2008 has been fully considered but is denied entry for the following reasons:

The amendment raises new issues that would require further search given that such limitations were never previously presented in the claims. While applicant's amendment would overcome the previous rejection under 35 U.S.C. 112, first paragraph if entered, the limitation wherein the composition comprises electrolyte concentrates rather than electrolytes raises new issues the would require further search.

The examiner notes that even *if* the amendment was entered, claims 1-8, 16 and 19-23 would be found unpatentable over Frankel ("Supplementation of Trace Elements in Parenteral Nutrition: Rationale and Recommendations") and claim 17 would be found unpatentable over Frankel in view of Ballevre et al. (US 2003/0161863).

While Frankel discloses compositions comprising a minimum provision of 50 meg/day (i.e. 0.05 mg/day) of selenium and 10 mg/day of zinc, Applicants submit that Frankel does not disclose that claimed ranges with sufficient specificity to lead one of ordinary skill in the art to choose the claimed selenium or zinc concentrations.

Note, Frankel discloses composition with a minimum of 0.05 mg/day selenium and even recommend, in cases of depletion, administering doses comprising 0.250 mg/day.

Applicants explain that they have previously demonstrated that the claimed invention involves surprising and unexpected results (see Rule 132 Declaration of D. Thomas Stifel dated December 28, 2009). Applicants find that they have clearly demonstrated "the compositions comprising high doses of selenium and zinc which are encompassed by the claims (i.e. selenium

does that are ten-fold higher than those discloses in the prior art),, are associated with a low risk of chronic inflammation, infections or diseases associated with free-radical production, as compared to low-dose compositions.

Applicants submit that the results described in the previously submitted Rule 132 declaration are reasonably commensurate in scope with the rejected claims. Applicants also submit that the comparison drug described in the declaration (i.e. Tracutil®) comprises a daily dose of 20 mg selenium and 3.27 mg zinc which is reasonably commensurate in scope with the closes prior art.

It is agreed that the results previously submitted are reasonably commensurate in scope with the rejected claims. However, Applicants have not shown that comparison samples in said examples fairly represent the closest prior art. It is well established that the evidence of unobviousness must be commensurate in scope with the claimed subject matter. See *In re Kerkhoven*, 626 F.2d 846, 851, 205 USPQ 1069, 1072-73 (CCPA 1980) and *In re Clemens*, 622 F.2d 1029, 1035, 206 USPQ 289, 896 (CCPA 1980). First the drug described in the declaration (i.e. Tracutil®) comprises 20 μg selenium and not 20 mg. A dose of 20 μg selenium, i.e. 0.002 mg, is over 10 times smaller than the minimum dose recommended by Frankel, i.e. 0.05 mg/day. Further, Frankel discloses a zinc dosage of 10 mg while Tracutil® comprises only 3.27 mg zinc. Clearly, the comparison drug described in the declaration (i.e. Tracutil®) ***does not*** represent the closest prior art.

In addition, while applicant has established that normal levels of selenium were achieved in the blood and serum of patient after administration of a composition comprising more selenium than a composition which did not produce normal levels of selenium, a person of

ordinary skill in the art would not find these results unexpected. One of ordinary skill in the art would expect that the greater the dose the faster normal levels of selenium in the blood and serum would be achieved.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH GWARTNEY whose telephone number is (571)270-3874. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./
Examiner, Art Unit 1781

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1781